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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/202,054	12/07/1998	AUDREY GODDARD	P1154R2	2403

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EXAMINER	
SPECTOR, LORRAINE	
ART UNIT	PAPER NUMBER
1647	22

DATE MAILED: 06/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.

EXAMINER	
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	22

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 3/17/03

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 28-30, 48-50, 54 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☒ Claim(s) 28-30, 48-50, 54 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

★ U.S. GPO: 1996-404-49

Part III: Detailed Office Action

Claim 51, introduced in the amendment filed 3/17/03, has been renumbered as claim 54. See 37 C.F.R. § 1.126.

Claims 28-30 and 48-50 and 54 are pending and under consideration.

Formal Matters:

The new title of the invention is acknowledged.

The rejection of claims 28-30 under 35 U.S.C. § 112, second paragraph, has been overcome by applicants amendments.

Objections and Rejections under 35 U.S.C. §101 and §112:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 28-30 and 48-51 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility. for reasons of record in the previous Office Action at pages 2-4. Applicants traversal of this rejection in paper number 20, submitted 3/17/03, has been fully considered but is not deemed persuasive.

At page 5 of the response, applicants argue that identification of a specific ligand is not an absolute requirement for finding utility of a newly identified receptor. While this is true, the point made in the rejection was that *if* a specific ligand *had* been identified, such might serve as sufficient to establish utility, however that is not the case here. There is no *requirement* that a ligand have been identified, the Examiner was merely making the point that identification of such a ligand is one of many things that *might* serve to establish utility.

At pages 5-6, applicants argue that the utility of the claimed antibodies can be established by reference to the role of the Toll family of polypeptides "in sensing microbial pathogens", and that "the unique homology exhibited by the Toll polypeptide family results from their functional role in mediating ancient defense mechanisms". This argument has been fully considered but is not deemed persuasive for two reasons. First, even *if* it is true that PRO285 plays a role in mediating defense against microbial pathogens, such is not, in and of itself sufficient to confer utility; the mere identification of a general role for a family of proteins does not teach one of ordinary skill in the art how to use *this* protein, PRO285, nor antibodies that bind to it. Substantial further investigation would be required to determine the *specific* function of PRO285 before any use within the meaning of 35 U.S.C. § 101 could be determined. It remains that there is no disclosed, readily available diagnostic or therapeutic use for the protein. Determination of the role of PRO285 and development of a use based on that role constitutes a substantial inventive contribution. Second, as stated in the previous Office Action, the assertion that anti-PRO285 antibodies can be used for the same purposes as anti-TLR2 antibodies would not be considered substantial or credible by one of skill in the art because such utilities have not been credibly established for TLR2, nor, even if they were, would such be predictive of homologous proteins such as PRO285. It is noted that when the sequence of PRO285 was searched against all available databases, that no significant homology to TLR2 was detected. Therefore, it would not be predictable that the two proteins, and hence antibodies that bind such, would share any specific structure or function. Applicants have not, in their response, pointed out any specific areas of similarity between the two proteins, nor other rationale that would support the assertion that PRO285 is sufficiently similar to TLR2 so as to be functionally related to such.

At pages 6-7 of the response, applicants argue that isolation of Toll homologues on the basis of homology is practiced in the art, and that "functional data relating to one Toll family member such as TLR2 can reasonably suggest functions of other Toll homologues", citing a paper by Du et al., published after the filing date of this application, in support of their argument. This argument has been fully considered but is not deemed persuasive because Du does not support that assertion. The

person of ordinary skill in the art would *not* accept an assignment of function based upon mere membership in the Toll family of proteins. To quote Du et al. at page 369, "The assignment of function to distinct members of the Tlr family is of paramount importance in this rapidly developing field. *We are able to draw no substantial inferences based on the distribution of TLR gene expression.*" (Emphasis added.) Continuing in the same paragraph, "The function of Tlr4 as an LPS receptor has been demonstrated by the identification of two naturally occurring mutations that render mice resistant to LPS, and subsequently was confirmed by knockout of the gene." Thus, Du et al. teach that sequence homology and expression information are *not* considered predictive of function by the person of ordinary skill in the art, and that substantial further experimentation, such as obtaining animals with specific mutations or knock-outs of the gene in question are the type of investigation that must be done to establish a specific function for a newly identified gene. Thus, the Examiner maintains that mere assertion that PRO285 is a member of the Toll family is not sufficient to support any of the asserted utilities as being substantial or credible.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-30 and 48-51 also remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Rejections Over Prior Art:

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the

basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 28 and 48 remain rejected under 35 U.S.C. 102(b) as being anticipated by Ruggeri et al., WO 91/09614.

Ruggeri et al. disclose a 19 residue peptide that matches SEQ ID NO: 2 at positions 704-712, a 9/15 match; see the third peptide listed in claim 1. At page 19 and in claim 65, antibodies to such peptides are disclosed and claimed.

Applicants argue that Ruggeri does not anticipate the claims because PRO285 is not taught. This argument has been fully considered but is not deemed persuasive because the degree of identity between the peptide of Ruggeri et al. and PRO285 would lead the person of ordinary skill in the art to the conclusion that antibodies to Ruggeri's peptide would necessarily bind to PRO285, due to the common 9 amino acid stretch, which is well-established in the art as being long enough to constitute an epitope. Accordingly, Ruggeri's antibodies would inherently bind PRO285. It is not necessary that Ruggeri have had any knowledge of PRO285 for anticipation to be found.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made

in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 29, and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruggeri et al., WO 91/09614, in view of Coughlin, U.S. Patent Number 5,256,766 for reasons of record in the previous Office Action. Applicants argument of Ruggeri is found not persuasive, for reasons cited above. Applicants have presented no separate argument of the obviousness rejection.

Claim 50 remains, and newly introduced claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ruggeri et al., WO 91/09614, in view of Coughlin, U.S. Patent Number 5,256,766, and further in view of U.S. Patent Number 4,946,778 (Ladner et al.) for reasons of record in the previous Office Action. With respect to claim 51, it is noted that single chain antibodies are chimeric in nature. Applicants argument of Ruggeri is found not persuasive, for reasons cited above. Applicants have presented no separate argument of the obviousness rejection.

Advisory Information:

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector, whose telephone number is (703) 308-1793. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 5:30 P.M.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary L. Kunz, at (703)308-4623.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist at telephone number (703) 308-0196.

Certain papers related to this application may be submitted to Group 1800 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to (703) 746-5228.

Lorraine Spector

Lorraine Spector, Ph.D.
Primary Examiner

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5/29/03